

A final order reclassifying shortwave diathermy (SWD) intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues, a preamendments Class III device, into class II, and renaming the device “nonthermal shortwave therapy” (SWT), was published on October 13, 2015. See here:

<https://www.federalregister.gov/documents/2015/10/13/2015-25923/physical-medicine-devices-reclassification-of-shortwave-diathermy-for-all-other-uses-henceforth-to>

While the device submitted and cleared through K093675 may serve as a valid predicate device for a new SWT device, please refer to the aforementioned final order for current regulatory requirements for this device type.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Vertebral Technologies, Inc.
% Suresh Ghai, Ph.D.
Director, Quality and Regulatory Affairs
5909 Baker Road, Suite 550
Minnetonka, Minnesota 55345

DEC 23 2009

Re: K093675

Trade/Device Name: InterFuse® Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888-3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: November 25, 2009
Received: November 27, 2009

Dear Dr. Ghai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

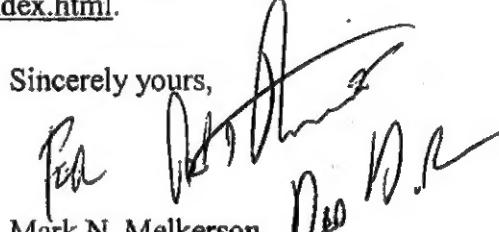
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. STATEMENT OF INDICATION FOR USE

Indication for Use

510(k) Number (If known): K093675

Device Name: InterFuse® Intervertebral Body Fusion Device

Indications for Use:

The InterFuse® Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

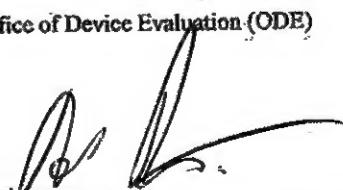
Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Vertebral Technologies, Inc.

InterFuse Intervertebral Body Fusion Device Special 510(k) Pre-market Notification
510(k) Number K093675

3. 510(k) SUMMARY

510(k) SUMMARY
[as required by section 807:92(c)]

DEC 23 2009

510(k) Owner's Name: Vertebral Technologies, Inc.

Address: 5909 Baker Road, Suite 550
Minnetonka, MN 55345

Phone/Fax/Email: Office: (952) 979-9357
Company Main Tel: (952) 912-5400
Fax: (952) 912-5410
Email: sghai@vti-spine.com

Name of Contact Person: Suresh Ghai, Ph.D.
Director, Quality and Regulatory Affairs

Date prepared: 25 NOV, 2009

Trade or Proprietary Name: InterFuse® Intervertebral Body Fusion Device

Common or Usual Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar
21 CFR § 888.3080
Product code: MAX
Device Class: II

3.1 LEGALLY MARKETED DEVICE TO WHICH YOUR FIRM IS CLAIMING EQUIVALENCE

The modified InterFuse® Intervertebral Body Fusion Device is substantially equivalent in performance, indication, design and material to VTI's own InterFuse® Intervertebral Body Fusion Device cleared under Premarket notification # K 080673.

3.2 DEVICE DESCRIPTION

VTI's Intervertebral Body Fusion device is made of PEEK (Poly ether ether ketone), a polymer with a history of use in interbody fusion device designs, and which has a compressive modulus similar to bone. Each segment of the device has embedded tantalum beads that aid in visualizing the implanted device under x-ray and to aid in position retention when assembled in the disc space. Each segment has an integral rail and/or slot which slide through or over the rail or slot in the adjacent segment to complete the device. Each segment incorporates a stop to help ensure that it is properly aligned with the adjacent segment. The exposed rail of each segment is removed after the adjacent segment is installed. The modular system allows for as

few as three segments to be used, although most patients will require between four and six segments for optimum coverage of the vertebral endplate. Each segment has a vertical slot through the device for the surgeon to fill with autogenous bone that will provide a path for solid bone growth during the fusion process. The device is produced in four heights (8, 10, 12 and 14 mm) and two anterior-posterior dimensions (20 mm and 25 mm) to fit a range of potential disc spaces. The device will also be produced in flat and 5° angled (lordotic) shapes to fit the angular geometry of the disc at each disc level.

3.5 INTENDED USE OF THE DEVICE

The InterFuse® Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse device is indicated for use with autogenous bone graft and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

3.6 TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE

The modified InterFuse® Intervertebral Body Fusion Device is substantially equivalent in performance, indication, design and materials to InterFuse® Intervertebral Body Fusion Device from our company (VTI), cleared under premarket notification # K080673. The modified device has 2 years shelf-life as compared to 6 months shelf-life of the unmodified device (K080673).

3.7 SUMMARY AND CONCLUSIONS FROM THE NONCLINICAL TESTS SUBMITTED

The substantial equivalence is supported by bench testing comparing the modified InterFuse® Intervertebral Body Fusion Device to the predicate device (K080673).

The design of the device has not changed from the 510(k) cleared device (K080673). The only change is the expiry date/shelf life on the labels. The modified device has 2 years shelf-life as compared to 6 months shelf-life of the unmodified device (K080673).

The two (2) years shelf-life is based on accelerated aging at 55°C carried out per ASTM F1980-07. At the end of the 2-year shelf-life, the packages were tested for seal integrity by peel test, dye penetration and bubble burst test. The performance of the aged devices was tested for static compression in accordance with ASTM F2077-03 – *Test methods for Intervertebral Body Fusion Devices*. The aged devices were also tested for cytotoxicity (ISO 10993-5) to detect any changes during aging. All tests met the acceptance criteria specified in the shelf-life testing protocol.

On the basis of performance data and packages testing it is concluded that the modified device is substantially equivalent to the unmodified device (K080673).